

<b>Institution: Newcastle University</b>
<b>Unit of Assessment: 23 Sociology</b>
<b>Title of case study: Bringing tissue providers' voices into the ethical governance of clinical research</b>
<p><b>1. Summary of the impact</b></p> <p>Clinical research is heavily dependent on individuals providing tissues for experimentation and therapeutic developments. Since the Declaration of Helsinki (1964) the ethical protection of tissue providers has been a central concern. However, tissue providers have rarely been included in designing those protections. Research at Newcastle (2001–2011) has contributed to changing this, since 2008 it has brought providers' perspectives to the attention of key audiences: clinical research funders, policy advisers, and practising scientists. In terms of significance and reach this research has:</p> <ul style="list-style-type: none"> <li>• impacted on guidelines for the ethical conduct of clinical research by adding a new perspective;</li> <li>• strengthened the guidance provided by two major international advisory bodies;</li> <li>• contributed to the ethical protection of over 500,000 research participants.</li> </ul>
<p><b>2. Underpinning research</b></p> <p><u>Researchers and funding</u></p> <p>Erica Haimes is Professor of Sociology (1998 to date), Executive Director of the Policy, Ethics and Life Sciences Research Centre (Newcastle University) and was Principal Investigator on three research projects funded by the Wellcome Trust and the Medical Research Council between 2001 and 2012.</p> <p><u>Context of the research</u></p> <p>The growing sophistication of genetics research means that biobanks (collections of human tissue samples and health information) have become increasingly useful for understanding the relationship between genes and diseases. However, biobanks raise profound concerns about 'informed consent' and privacy. Scientists have tended to assume that tissue providers are simply altruistic donors. This same assumption has been made about women who provide eggs and embryos for stem cell research. Celebrated as one of the most promising means of tackling currently incurable diseases, stem cell science requires human eggs and embryos for its development and this has led to heated ethical and public debate. Such debates have largely been conducted in abstract and rarely include the perspectives of the women who provide that tissue. Research in Newcastle aimed to change and improve these ethical debates through empirical investigations of tissue providers' views <b>(1)</b>.</p> <p><u>Research</u></p> <p>Study 1 (2001–3) investigated pregnant women's considerations when deciding whether to contribute afterbirth to the North Cumbria Community Genetics research biobank. Analysis of interviews with women who did, and did not, provide tissue demonstrated <b>(2)</b> that:</p> <ul style="list-style-type: none"> <li>• preoccupation with the imminent birth meant women did not realize they had consented to provide tissue;</li> <li>• women thought the afterbirth was waste material, not realizing it contained genetic information about their child;</li> <li>• 'consent' and 'altruism' were therefore superficial descriptions of women's actions and motivations.</li> </ul> <p>Study 2 (2004–12) was the world's first investigation of IVF patients' experiences of providing embryos for stem cell research, at a time when ethical and political debates focused on the moral status of human embryos. The study revealed <b>(3)</b> that:</p> <ul style="list-style-type: none"> <li>• patients imbued embryos with highly variable social and moral significance, depending on their usefulness for achieving a much-desired pregnancy;</li> </ul>

## Impact case study (REF3b)

- patients' views of embryos changed as they progressed through IVF;
- therefore better informed consent to giving embryos to research depended on previous IVF experience rather than standard informed consent procedures;
- embryo providers require as much ethical protection as, if not more than, embryos.

Study 3 (2008–11) was another 'world first', a socio-ethical investigation of a scheme in which private IVF patients were offered reduced fees if they gave eggs to stem cell-related research. The global demand for human eggs for research has raised concerns about undue inducements and exploitation of poorer women. This project demonstrated that **(4, 5)**:

- patients struggled to access sufficient IVF treatment because of expensive private fees and scarcity of NHS provision;
- they therefore welcomed the scheme, while also proving capable of resisting inducement and avoiding exploitation;
- a willingness to provide eggs for research has to be understood within the local context of funding and provision of, and demand for, IVF treatment;
- caution therefore needs to be exercised before extending such schemes globally.

These pioneering projects demonstrate that:

- i. tissue providers' perspectives should be included in designing ethical frameworks for the conduct of science;
- ii. the social contexts of requests for tissue influence potential providers' evaluations of the significance of, and responses to, those requests;
- iii. the moral significance of human tissue varies according to social context;
- iv. applied sociological research enhances understandings of core ethical concepts such as 'altruism', 'consent', 'inducement' and 'exploitation' **(6)**.

### 3. References to the research

- 1) Haimes, E. (2002) 'What can the social sciences contribute to the study of ethics? Theoretical, empirical and substantive considerations', *Bioethics*, 16 (2): 89-113.  
DOI: <http://dx.doi.org/10.1111/1467-8519.00273>. [Reprinted in Chadwick, R., Kuhse, H., Landman, W., Schüklenk, U. and Singer, P. (eds) (2007) *The Bioethics Reader: Editors' Choice*, (Oxford: Blackwell, pp.33-52), a collection of the editors' choice of the top papers published in *Bioethics* over the previous 20 years.]
- 2) Haimes, E. and Whong-Barr, M. (2004) 'Levels and styles of participation in genetic databases: a case study of the North Cumbria Community Genetics Project' in Tutton, R. and Corrigan, O. (eds) *Donating, Collecting and Exploiting Human Tissue: Social and Ethical Dimensions of Genetic Research*, London: Routledge, pp.57-77. [Edited book with prestige and profile in the field. Hard copy available on request.]
- 3) Haimes, E., Porz, R., Scully, J. and Rehmann-Sutter, C. (2008) "So, what is an embryo?" A comparative study of the views of those asked to donate embryos for hESC research in the UK and Switzerland' *New Genetics and Society*, 27 (2):113-126. [REF2 output 76628, DOI: <http://dx.doi.org/10.1080/14636770802077041>]
- 4) Haimes, E, Taylor, K. and Turkmendag, I. (2012) 'Eggs, ethics and exploitation? Investigating women's experiences of an egg sharing scheme', *Sociology of Health and Illness*, 34 (8): 1199-1214. [REF2 output 189408, DOI: <http://dx.doi.org/10.1111/j.1467-9566.2012.01467.x>]
- 5) Haimes, E. (2013) 'Juggling on a rollercoaster? Gains, loss and uncertainties in IVF patients' accounts of volunteering for a UK 'egg sharing for research' scheme', *Social Science and Medicine*, 86: 45-51. [REF2 output 191697, DOI: <http://dx.doi.org/10.1016/j.socscimed.2013.03.002>]
- 6) Haimes, E and Williams, R. (2007) 'Sociology, ethics and the priority of the particular: learning from a case study of genetic deliberation', *British Journal of Sociology*, 58 (3):457-476. [Shortlisted in April 2009 for BJS Prize for 'outstanding contributions to increasing sociological knowledge', DOI: <http://dx.doi.org/10.1111/j.1468-4446.2007.00160.x>]

Research grants:

Principal Investigator	Grant Title	Sponsor	Period of Grant	Value
Erica Haimes	Reasons for participation and non-participation in genetic databases	Wellcome Trust	2001-2003 (16 months)	£73,003
Erica Haimes	Potential embryo donors' views on embryonic stem cell research and therapies	Wellcome Trust	2004-2012	£210,944
Erica Haimes	Women's experiences of an IVF egg sharing scheme for SCNT research	Medical Research Council	2008-2011 (36 months)	£296,000

#### 4. Details of the impact

The underpinning research demonstrated that providers' voices bring important new perspectives to the design of ethical protections in the conduct of clinical research. It was used to inform and enrich the understandings of several diverse and important communities, including those funding, conducting and advising on the ethics of, clinical research.

**(1) Contributing to the design and implementation of ethical protection of tissue providers in UK Biobank:** UK Biobank is an on-going national collection of tissue and information donated by over 500,000 people to be used in research to improve the prevention, diagnosis and treatment of a wide range of serious and life-threatening illnesses.

**Pathway to impact:** In 2003, following dissemination of Study 1, Haimes was appointed to the Interim Advisory Group of the UK Biobank by the Wellcome Trust and the Medical Research Council. The Head of MRC's Corporate Governance & Policy said that the findings from Study 1 were '*recognised by myself and my colleague at the Wellcome Trust... to be highly relevant to our discussions about the recruitment of, and establishing ethical protection for, participants in the UK Biobank... This is why we invited [Haimes] to be one of a small group of 9 people to form the Interim Advisory Group (Ethics and Governance) for UK Biobank*' (**IMP1**). This Group wrote, from scratch, the Ethics and Governance Framework (**IMP2**), a set of principles to guide UK Biobank's relationship with tissue providers including the establishment of an Ethics and Governance Council to oversee UK Biobank. Individuals' contributions to the Interim Advisory Group's deliberations were not minuted (**IMP3**); however, as the only social scientist and the only person who had conducted research with tissue providers, Haimes clearly enhanced the Group's capacity to develop effective guidelines. This was confirmed by a fellow Group member who then became Chair of the Ethics and Governance Council:

*'During the deliberations of the Interim Advisory Group Professor Haimes drew extensively on findings from her research with tissue donors to the North Cumbrian Community genetic database to alert the rest of the Group to considerations and experiences that donors themselves brought to the process of deciding whether to provide tissue to clinical research. This evidence closely informed our drafting of the section of the Ethics and Governance Framework that addressed the relationship of UK Biobank to its tissue donors...'* (**IMP4**).

**Impact:** UK Biobank recruited participants between 2007–10 and its data and samples were made available to researchers in late 2011. Throughout this time the Ethics and Governance Framework has been used '*to set standards...and to ensure that safeguards are in place for scientifically and ethically approved research*'. The Ethics and Governance Council is used '*to oversee UK Biobank's adherence to the Framework*' (**IMP2**). Haimes was appointed to the Ethics and Governance Council (Jan 2007–Dec 2009), which benefited from Newcastle research as noted by the then Chair:

*'[Haimes] brought her research findings from three related projects directly to bear on, and informed and enriched our understandings of, a number of different topics. ... As the only social scientist on the EGC conducting relevant empirical studies, Professor Haimes played a central role... [in providing insights into potential participants' views on]... questions of third party access to the biobank, the commercialisation of results... and the possibility of "benefit sharing" by participants...'* (**IMP4**).

In terms of significance and reach, the underpinning research from Newcastle University has made a major contribution to reducing the risks of participation in UK Biobank for over 500,000 tissue donors and continues to influence decisions on access to samples and data.

**(2) Contributions to Nuffield Council on Bioethics' policy advice on the ethics of encouraging donations of human tissue to research:** The Nuffield Council on Bioethics (NCoB) is a highly influential, independent body that examines and reports on ethical issues in the life sciences; it has an international reputation for advising policy makers. The NCoB has made active use of Newcastle's research on tissue providers in its Working Party's deliberations on the ethics of encouraging people to donate human tissue for clinical research and treatment. In December 2008 they invited Haimes to present to a closed workshop on 'Volunteering, donation and payment in the clinical context' to stimulate discussion on the social aspects that should be taken into consideration. The Director of the NCoB reports: '*This presentation raised, for the first time in our considerations of this subject, a number of issues that were to prove significant in the later work of the Working Party*' (IMP5).

In November 2010, Haimes was invited to contribute further to the Working Party's deliberations, through participation in a six-person forum on 'The conflict between public and private "good" in the donation of tissue to research and therapy'. Study 3 was at the centre of her presentation and hand-out, examples from which were featured in the Final Report on pages 123 and 221. The Final Report also cites the Newcastle research on pages 112 and 182 (IMP6). Further evidence of the benefit gained by, and influence on, the NCoB from Haimes' research comes from her appointment as a full Council member in 2013.

**(3) Writing a Position Statement for a global organisation of practising scientists:** Haimes' worldwide dissemination of the underpinning research led to an invitation in 2009 to join the international Ethics and Public Policy Committee of the International Society for Stem Cell Research (ISSCR) (IMP7). The ISSCR is an independent, non-profit organization with 3,500 members worldwide; it is recognised as the voice of the stem cell research community. Using the underpinning research, Haimes is enhancing the Ethics Committee's considerations of the best ways to protect the interests of individuals providing tissue for stem cell research.

In particular, throughout 2011–12 Haimes led the Committee's discussions, and the drafting of a report, on ethical approaches to recruiting egg donors for stem cell research. The then Chair of the Ethics and Public Policy Committee says, '*Haimes' membership of the Committee transformed our general discussions... into a focused strategy for bringing the ethical issues around egg providers' interests to the attention of the practising scientists who form the membership of the ISSCR*' (IMP8). The Chair notes '*the leading role*' played by Haimes in the adoption of that report as a formal Position Statement by the ISSCR as a whole (IMP9), meaning that this will now act as a socio-ethical guideline to which all ISSCR scientists will be expected to adhere.

## 5. Sources to corroborate the impact

- (IMP1) Correspondence, Head of Corporate Governance & Policy, the Medical Research Council.
- (IMP2) UKBiobank Ethics and Governance Framework. [www.ukbiobank.ac.uk/ethics/](http://www.ukbiobank.ac.uk/ethics/)
- (IMP3) Interim Advisory Group's own document (WTD003287) to corroborate pathways to impact available at <http://www.wellcome.ac.uk/search-result.htm?q=WTD003287>.
- (IMP4) Correspondence, former Chair, UK Biobank Ethics and Governance Council.
- (IMP5) Correspondence, Director, the Nuffield Council on Bioethics.
- (IMP6) NCoB Report (2011) 'Human Bodies: donation for medicine and research', available at <http://www.nuffieldbioethics.org/donation>.
- (IMP7) Invitation to join the International Society of Stem Cell Research Ethics and Public Policy Committee.
- (IMP8) Correspondence, Chair, the ISSCR Ethics and Public Policy Committee.
- (IMP9) Haimes, E. et al (2013) 'Position Statement on the provision and procurement of human eggs for stem cell research', *Cell Stem Cell*, 12: 285-291, March. <http://dx.doi.org/10.1016/j.stem.2013.02.002>.

Copies of correspondence for items 1, 4, 5, 7 and 8 are available on request.